



**[BILLING CODE 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request; Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report. Office of the Director (OD).**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of Laboratory Animal Welfare (OLAW) in the Office of Extramural Research has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. The purpose of this notice is to allow 60 days for public comment.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To submit comments in writing or request more information on the proposed collection, contact: Eileen M. Morgan, Director, Division of Assurances, Office of Laboratory Animal Welfare, NIH, call (301) 594-2289 or email your request to [olawdocs@mail.nih.gov](mailto:olawdocs@mail.nih.gov). Formal requests for information collection forms must be requested via email to [olawdocs@mail.nih.gov](mailto:olawdocs@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the

function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report, OMB#0925-NEW, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: The Office of Laboratory Welfare (OLAW) is responsible for the implementation, general administration, and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) as codified in 42 CFR 52.8. The PHS Policy implements the Health Research Extension Act (HREA) of 1985 (Public Law 99-158 as codified in 42 U.S.C. 289d). The PHS Policy requires entities that conduct research involving vertebrate animals using PHS funds to have an Institutional Animal Care and Use Committee (IACUC), provide assurance that requirements of the Policy are met, and submit an annual report. An institution's animal care and use program is described in the Animal Welfare Assurance (Assurance) document and sets forth institutional compliance with PHS Policy. The purpose of the Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report is to provide OLAW with documentation to satisfy the requirements of the HREA, illustrate institutional adherence to PHS Policy, and enable OLAW to carry out its

mission to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

OMB approval is requested for 3 years. The total estimated annualized burden hours are 8,140.

#### Estimated Annualized Burden Hours

Document	Type of Respondents	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Annual Burden Hours
Interinstitutional Assurance	Foreign	40	1	30/60	20
Interinstitutional Assurance	Domestic	660	1	30/60	330
Foreign Assurance	Renewal and New	60	1	1	60
Domestic Assurance	Renewal	220	1	26	5,720
Domestic Assurance	New	20	1	30	600
Annual Report	All Domestic	940	1	90/60	1,410
TOTAL			1,940		8,140

Dated: June 11, 2019.

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Lawrence A. Tabak,

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[FR Doc. 2019-12734 Filed: 6/14/2019 8:45 am; Publication Date: 6/17/2019]